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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
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| 10/027,877 | 12/19/2001 | William Earl Webler | 5618P2977 | 1005 | |
| 8791 7 | 590 05/23/2006 | | EXAM | EXAMINER | |
| BLAKELY SOKOLOFF TAYLOR & ZAFMAN | | | FOREMAN, JO | FOREMAN, JONATHAN M | |
| 12400 WILSHIRE BOULEVARD SEVENTH FLOOR | | ART UNIT | PAPER NUMBER | | |
| LOS ANGELE | s, CA 90025-1030 | | 3736 | | |

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant/s) | | | | |
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| | | Applicant(s) | | | | |
| Office Action Summary | 10/027,877 | WEBLER, WILLIAM EAR | L | | | |
| JJor. Janimary | Examiner M. Sanara | Art Unit | | | | |
| The MAILING DATE of this communication app | Jonathan ML Foreman | 3736 orrespondence address | | | | |
| Period for Reply | and dovor sheet with the C | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on 27 Ap | <u>oril 2006</u> . | | | | | |
| ,— | · | | | | | |
| • | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| closed in accordance with the practice under E | x parte Quayle, 1935 C.D. 11, 45 | 3 O.G. 213. | | | | |
| Disposition of Claims | | | | | | |
| 4) ☐ Claim(s) 1.3-20 and 26 is/are pending in the ap 4a) Of the above claim(s) is/are withdraw 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1.3-20 and 26 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or | vn from consideration. | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) access applicant may not request that any objection to the confidence of the c | epted or b) objected to by the Eddrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj | e 37 CFR 1.85(a). lected to. See 37 CFR 1.12 | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some col None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | | | | | |

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DETAILED ACTION

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Claim Rejections - 35 USC § 112

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 2. Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 3 and 4 depend from a cancelled claim, therefore it is impossible to construe the scope of the claims. However, for the purposes of this examination, it has been assumed that claims 3 and 4 each depend from claim 1.

Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claims 1, 3, 5 9, 11, 12, 14 20 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,063,085 to Tay et al. in view of U.S. Patent No. 6,539,792 to Lull et al.
- In regards to claims 1, 3, 5-9, 11, 12, 14-20 and 26, Tay et al. discloses an elongate member as a needle, in that Tay et al. discloses the probe as a hollow elongated member (Col. 20, lines 12-18), or rod insertable into a body; a thermally conductive heating element coupled to the distal portion of the elongate member, the heating element comprising a wire whose electrical resistance changes in response to a change in temperature (Col. 20, lines 45-49). The needle

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includes a distal opening, and a lumen (148; Figure 21) extending from a proximal end to the distal opening (Col. 16, lines 12-15) in communication with the distal opening capable of allowing a substance to be delivered through the lumen. The distal end of the needle is capable of puncturing skin (Col. 15, line 65 - Col. 16, line 1). Tay et al. discloses anemometry circuitry and comparing a first resistance and a second resistance of the at least one heating element to indicate a change of conditions related to a distance of penetration of the heating element (Col. 20, lines 48 - 54). Tay et al. discloses an outer diameter between 0.009 inches and 0.134 inches (Col. 19, line 56 - Col. 20, line 18). The heating element is less than the thickness of the tissue in which it is inserted. In order to operate the device as disclosed by Tay et al. must include a first and second lead coupled to the at least one heating element. However, Tay et al. fails to disclose the anemometry circuitry comprising the heating element and a variable resistor as resistive circuit element. Nor does Tay et al. disclose an amplifier coupled to the circuit to amplify the voltage difference sensed between the heating element and the variable resistor, and to input the voltage difference back to the circuit to modify the temperature of the heating element such that the heating element assumes a second resistance. Lull et al. teaches a circuit for use in an anemometer (Col. 17, lines 10 - 15) comprising a balanced circuit (Col. 11, lines 40 – 46) having the heating element (R_1, R_2) and a variable resistor (Col. 7, lines 49 - 52) as resistive circuit element and an amplifier coupled to the circuit to amplify the voltage difference sensed between the heating element and the variable resistor, and to input the voltage difference back to the circuit to modify the temperature of the heating element such that the heating element assumes a second resistance (Col. 7, line 25 – Col. 8, line 22). Lull et al. discloses anemometry circuitry separately coupled to each of the heating elements. It would have been obvious to one having ordinary skill in the art to modify the circuitry as disclosed by Tay et al. to include an interface to the balanced circuit as disclosed by Lull et al. in order to compare variations

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in the resistance of the heating elements (Col. 17, lines 10 – 15). Tay et al. fails to disclose the heating element being between 0.010 inches and 0.400 inches. However, a change in the size of a prior art device is a design consideration within the skill of the art. In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955). In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984),

cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

- 6. Claims 4 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,063,085 to Tay et al. in view of U.S. Patent No. 6,539,792 to Lull et al. as applied to claims 2 and 11 above, and further in view of U.S. Patent No. 3,470,604 to Zenick.
- 7. In reference to claims 4 and 13, Tay et al. in view of Lull et al. discloses a needle, but fails to disclose the needle being formed of stainless steel. However, stainless steel is well known in the medical industry for its strength, durability, ease of sterilization etc. Zenick discloses a hypodermic needle that is formed of stainless steel (Col. 1, line 65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the needle as disclosed by Tay et al. in view of Lull et al. out of stainless steel as taught by Zenick in order to have a sturdy, durably and easily sterilized hypodermic needle for insertion into a patient.
- 8. Claims 10 and 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,063,085 to Tay et al. in view of U.S. Patent No. 6,539,792 to Lull et al. as applied to claims 1 and 14 above, and further in view of U.S. Patent No. 5,873,835 to Hastings et al.
- 9. In regards to claims 10 and 18, Tay et al. in view of Lull et al. fails to disclose the forming the elongate member of an electrically conductive material and coupling the first end of the heating element to an electrically conductive lead and coupling the second end of the heating element by the elongate member. Hastings et al. teaches a portion of the elongate member being electrically

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conductive and the anemometry circuitry interface comprising an electrically conductive lead electrically coupled to a first end of the heating element, and the elongate member electrically coupled to a second end of the heating element (Col. 11, lines 33 - 35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the elongate member as disclosed by Tay et al. in view of Lull et al. to be an electrically conductive material and coupling the first end of the heating element to an electrically conductive lead and coupling the second end of the heating element by the elongate member as taught by Hastings et al. in order to reduce the resistance of the electrical connections to the heating element (Col. 11, lines 33 - 35).

Response to Arguments

10. Applicant's arguments filed 4/27/06 have been fully considered but they are not persuasive. In regards to the claims being rejected under 35 U.S.C. § 103 (a) as being obvious over US Patent No. 6,063,085 to Tay et al. in view of US Patent No. 6,539,792 to Lull et al., Applicant asserts that a prima facie case of obviousness has not been established. However the Examiner disagrees. As Applicant has pointed out, in order to establish a prima facie case of obviousness: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference; (2) there must be a reasonable expectation of success; and (3) the references when combined must teach or suggest all of the claim limitations. MPEP 2142. The Examiner asserts that Tay et al. in view of Lull et al., when combined, teach or suggest all of the claim limitations (See Paragraph 5 above). The Examiner asserts that there is a reasonable expectation of success in that merely one anemometry circuit has been replaced by another. Each anemometry circuit as disclosed by Tay et al. and Lull et al. is used to compare a first resistance and a second resistance of at least one heating element. The

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Examiner asserts that the suggestion or motivation to combine Tay et al. and Lull et al. is found in the references themselves or in the knowledge generally available to one having ordinary skill in the art. At Col. 20, lines 43 – 54, Tay et al. teaches that other techniques may be used to determine the depth of a vessel wall. Tay et al. suggests using a flow anemometer, which comprises two thin coils of wire spaced slightly apart on a probe and heated by passing electrical current there through, causing resistance heating. By constructing the coils out of wire with a temperature-dependent resistance, the position of the probe with respect to the vessel can be determined by comparing the resistance between the two coils, because blood flow past a coil within the artery will reduce its temperature, and hence its resistance, compared to a coil outside of the artery. However, Tay et al. fails to disclose any specific circuitry to control the anemometer. As a result, one having ordinary skill in the art would look towards the prior art for a circuit to control an anemometer.

Conclusion

11. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MAX F. HINDENBURG SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 3700

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